

REMARKS

A. Status of the Claims

Claims 1-18 are currently pending in the present patent application.

B. Claim rejections under 35 U.S.C. § 102

Claims 1-18 stand rejected under 35 U.S.C. § 102(b) as being allegedly anticipated by Sinderby (WO 02/056818, hereinafter "Sinderby'818"). Applicant respectfully traverses all rejections for the following reasons.

The present application comprises two independent claims -- method claim 1 and device claim 10.

Claim 1 recites a method for determining a level of ventilatory assist to a ventilator-dependent patient. A critical threshold of a respiration-related feature is calculated on a basis that fatigue of a respiratory muscle of the ventilator-dependent patient develops when the critical threshold is reached by the respiration-related feature. The level of ventilatory assist to the ventilator-dependent patient is controlled in relation to the critical threshold of the respiration-related feature so as to prevent fatigue of the patient's respiratory muscle. Device claim 10 includes similar limitations

Thus, both independent claims 1 and 10 recite a "critical threshold" that is related to "fatigue of a respiratory muscle of the ventilator-dependent patient." This relationship appears nowhere in the applied prior art, either expressly or inherently as presented in more detail below.

Sinderby'818 describes a method and a system for regulating airway leaks occurring between a ventilator circuit and respiratory airways during lung ventilatory support in response to myoelectrical activity of the patient's diaphragm, indicative of respiratory effort. Regulation is made by sealing leaks when a myoelectrical (EMGdi) signal is higher than a certain threshold.

As expressed in Sinderby'818, page 26 lines 3-7, an increase of the EMGdi signal amplitude above a desired threshold level, maintained for a desired duration, "can be used to indicate the onset of an inspiratory effort". This threshold is then used to determine when a normal inspiration flow is initiated. Throughout Sinderby'818, other mentions of "threshold" are also consistent with detection of inspiratory effort.

Meeting the threshold in Sinderby'818 does not reveal that fatigue of a patient's respiratory muscle occurs.

There is in Sinderby'818 no notion of a "critical threshold" as set forth in claim 1.

In fact, Sinderby'818 makes no mention of "fatigue", "tiredness", or any similar concept. Consequently, Sinderby'818 does not teach any relationship between a critical threshold and a level of fatigue of a respiratory muscle. Moreover, Sinderby'818 does not teach a control of ventilatory assist in relation to a critical threshold. Sinderby'818 does not teach a manner of preventing fatigue. In the text of the Office Action, the mention that "electrical signals from measurement probe 12 which are proportional to the fatigue of a respiratory muscle" is thus conclusory and entirely unsubstantiated by the disclosure of Sinderby'818.

The Office Action reads, in the middle of page 2, "In regard to claims 1-9, the method as claimed would be inherent during normal use and operation of the device". The MPEP section 2112 defines requirements for rejections based on inherency. The following passages are extracted from MPEP 2112 (*emphasis in original*):

IV. EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY

The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); *In re Oelrich*, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson*, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999). (...)

"In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990).

The finding of anticipation fails as a matter of law because it is based on a mere allegation that Sinderby'818 may support calculating a critical threshold related to fatigue, that such a threshold may be used to control a level of ventilatory assist, or that fatigue may be prevented.

There is in Sinderby'818 no clear indication that a person of ordinary skill in the art would recognize that fatigue may be related to a threshold, let alone to a critical threshold. Nothing in Sinderby'818 suggests that a threshold related to fatigue is necessarily present.

The mere fact that tracking a respiratory effort is taught in Sinderby'818 is not sufficient to demonstrate that fatigue could form a basis for calculating a critical threshold or that such a critical threshold could be used to control a level of ventilatory assist and to thereby prevent fatigue.

The Examiner has therefore not provided any factual basis or technical reasoning to reasonably support that calculation of a critical threshold related to fatigue of a respiratory muscle would necessarily flow from the teachings of Sinderby'818. As such, a *prima facie* demonstration of anticipation has not been provided in the outstanding Office Action.

For those reasons, Applicant respectfully submits that the subject matter of claim 1 is patentable over the teaching of Sinderby'818. Withdrawal of the rejection is kindly requested.

Claim 10 shares a comparable scope as that of claim 1; the above arguments have been presented in relation to claim 1 but equally apply to claim 10. Applicant thus submits that claim 10 is patentable in view of Sinderby'818.

Claims 2-9 depend directly or ultimately from patentable claim 1. Claims 11-18 depend directly or ultimately from patentable claim 10. Applicant respectfully submits that these claims should be found patentable at least because they depend on allowable bases.

C. Conclusion

Applicants believe this to be a complete response to the Office Action dated May 11, 2011. In light of the foregoing remarks, favorable reconsideration and timely allowance is respectfully requested.

Should the Examiner believe that a phone interview could expedite prosecution of the present application, he is invited to contact the undersigned patent attorney at (512) 536-3005 with any questions, comments or suggestions relating to the referenced patent application.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'David D. Bahler', with a long horizontal flourish extending to the right.

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